PT. SINKO PRIMA ALLOY

Alamat	: Jl. Tambak Osowilangun Permai No. 61, pergudangan osowilangun permai Blok E7-E8, Surabaya-Indonesia (60191)
Telepon	: 031-7482816
Fax.	: 031-7482815
Aftersale (WA)	: 0821-4281-7085
Email	: aftersales@elitech.co.id sinkoprima@gmail.com
Website	: www.elitech.id

SPA-BM/PROD-211. 11 Desember 2025. Rev02

Contents

A. Product Introduction

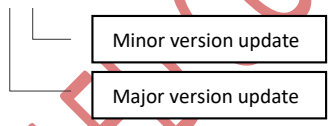
Welcome to the introduction of HRA Portable-01. Utilizing the low-voltage direct-current (DC) stimulus response technique, the HRA Portable-01 sends low-voltage DC stimulus signals to 22 body parts, obtains the electrical conduction value between electrodes, and records the instant electrophysiological status of the examinee. HRA Portable-01 is composed of the console (laptop, data acquisition unit with hand and foot electrodes installed), disposable head electrodes, head electrodes cable, hand electrodes and leg electrodes connector cable, and power adaptor.

B. Software Version

Complete version of software: V1.0

Release version of software: V1

Naming rule of software version: V X.X



C. Working Principle

Using the low-voltage DC stimulus response technique, the HRA system alternately sends the low-voltage (1.3 V) DC stimulus signal to 22 body parts at the mean frequency of 255 times/3seconds through 6 symmetrical electrodes at the head, the hand and the foot. This signal is turned into the ion current in the tissue. The electrical conductivity is obtained according to the polarization movement of the ion current in the skin tissue between the negative and the positive pole. The intensity change of 22 body parts/paths is recorded after stimulus signals are sent.

D. Intended Use

The device is for the measurement of galvanic skin response.

E. Product Specification

(1) The Product's Requirements for Normal Operating Environment

a. Environment temperature: 5 ℃ - 40 ℃;

b. Relative humidity: 10%RH-90%RH;

c. Power supply: AC 110 V-240 V, 50 Hz/60 Hz;

d. Safety class: Class II, Type BF applied part;

e. Atmospheric pressure: 860 hPa-1060 hPa.

(2) The Product's Requirements for Transportation and Storage Environment

a. Environment temperature: -40℃-55℃;

b. Relative humidity: 10 %RH – 95 %RH;

c. Atmospheric pressure: 700 hPa-1060 hPa.

(3) Electrodes

a. Disposable head electrodes

b. Hand electrodes: length × width: 210mm×130mm; material: 304 stainless steel;

c. Foot electrodes: length × width: 260mm×130mm; material: 304 stainless steel.

(4) Noise

Less than 60dB(A).

(5) Measurement range of skin conductivity

0-120μS.

(6) Data acquisition time

±390s.

(7) Output voltage

±1.3V.

(8) Size and weight of equipment

Size：480*390*75mm; Weight：±5kg.

(9) Console system

Win 10 operating system.

(10) Applicable standards

IEC 60601-1; IEC 60601-1-2.

(11) Protection of defibrillation charge effect

No.

(12) Permanently installed device or non-permanently installed device

Non-permanently installed device.

(13) Symbols

Symbol	Meaning	Symbol	Meaning
	Manufacturer		Type BF applied part The entire Wearable Sensor isa type BF applied part
	Date of manufacture		Follow instructions for use
	Batch number		Serial number
	Keep away from sunlight		Fragile, handle with care
	Disposal of electrical and electronic equipment		Authorized representative in the European Community
	CE mark		Indoor use only. Protect the device against dust andmoisture.
	Atmospheric pressure limitation		Temperature limitation
	Humidity limitation		Keep dry
	Caution: consult accompanying documents		Class II equipment

F. Contraindications

(1) Those with the cardiac pacemaker;

(2) Those with severe cardiac insufficiency;

(3) Those with severe skin disease;

(4) Those having metal foreign matters (including cardiac and pulmonary artery stent);

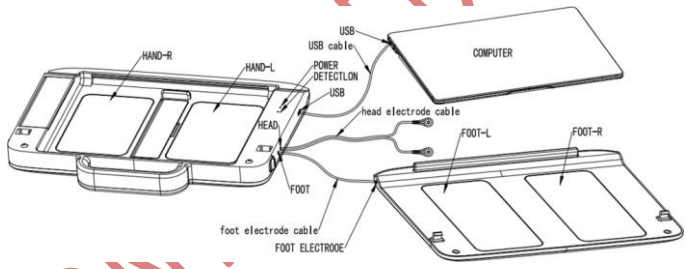
(5) Those having skin damage at the palm, the foot and the forehead;

(6) Pregnant women;

(7) Those who took steroids and have taken analgesics for a long term.

G. Main Structure

The HRA system is composed of the console (computer, display, data acquisition unit, hand and foot electrodes, and auxiliary display), disposable head electrodes, the connecting line of head electrodes, and the power line, as shown in the figure below:



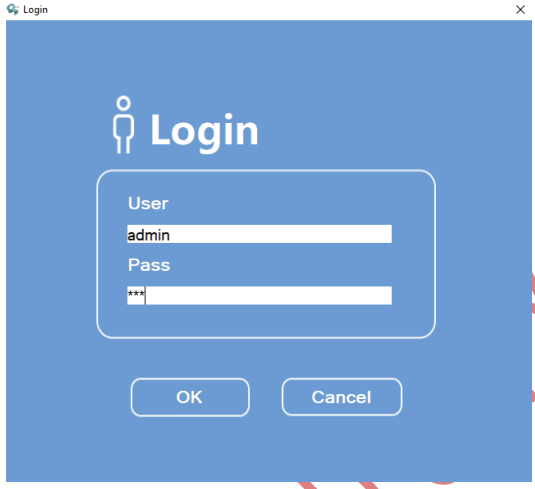
H. Instructions

(1) Starting up

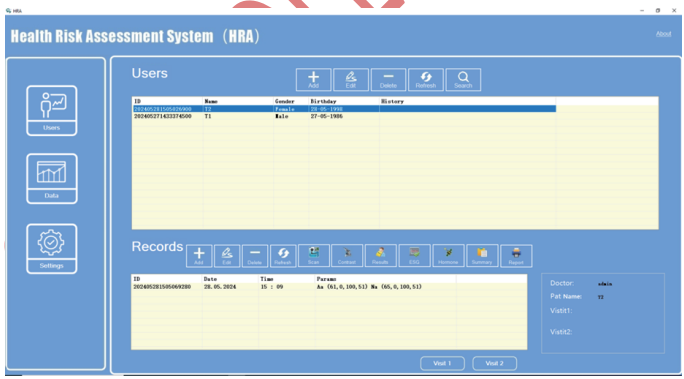
a. Connect the power, turn on the power switch and the power indicator lights up;

(2) Start the software

a. Double click the HRA software icon to pop up the following login interface:

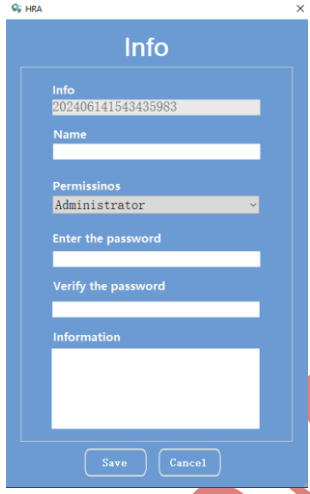


b. If the device is used for the first time, enter "admin" in the "User " field, enter “123” in the “Pass”. Click "OK" to log in. This user name is factory settings. After logging in to the system, the interface shown below is displayed.



c. Multiple separate usernames and passwords can be set up in the system. Each user has his/her own examine database. Add a new user (“admin only”): click “Settings”.

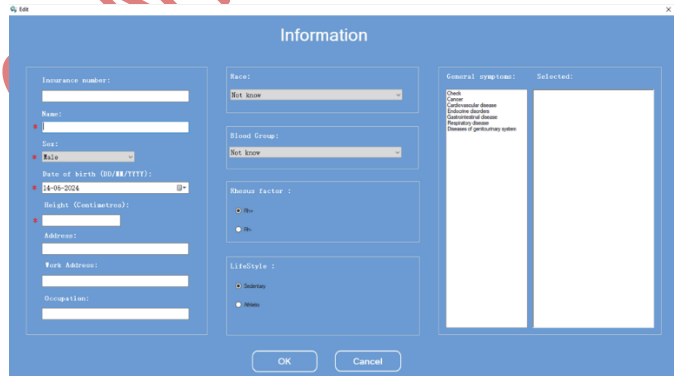
click “Add”, fill in the form, input information of the new user, click “OK”, reopen the software to log in with the new username and password.



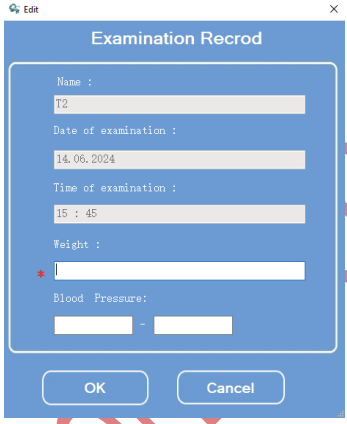
(3) Examinee registration

a. New member

① When the establishment of the administrator is completed and the device hardware detection has no problem, the information of the new member can be established. Click the "New Member" button in the toolbar to pop up the new member information form interface, where "name", "gender", "date of birth" and "height" are required. Other items are optional. After filling in the information. Click the "OK" button to complete the creation of the new member profile:



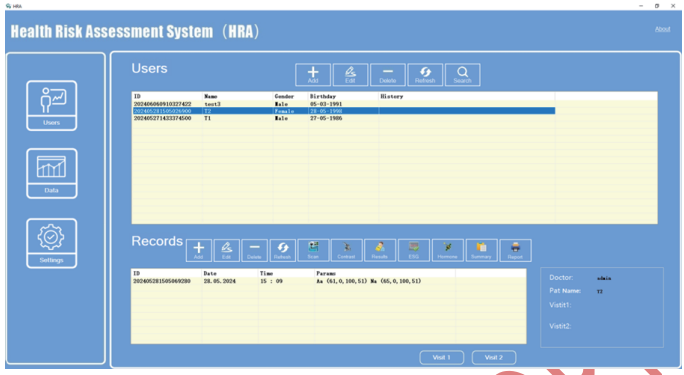
② After entering the member information, the parameter registration screen will pop up, as shown in the following picture. after filling in the weight, the "check date" and "check time" are automatically generated by the system and need not be changed, the "weight" item is required, the "blood pressure" item is optional, if you fill in the blood pressure parameter, fill in the diastolic blood pressure parameter in the first blank, fill in the systolic blood pressure parameter in the second blank, and then click "OK" button to complete the registration of new members' body information parameters:



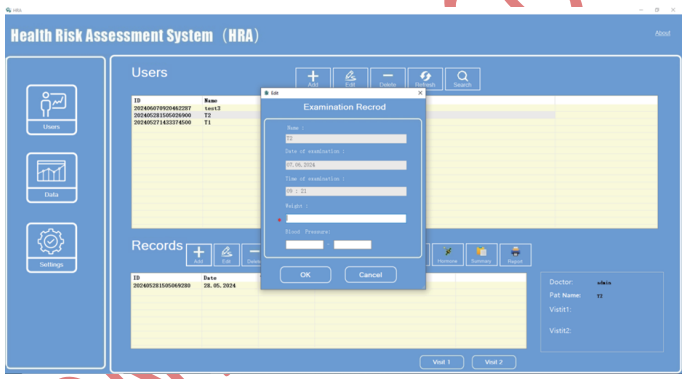
b. Registered member

① For registered members, when testing again, you do not need to fill in the member information, you can directly select the member's information and fill in the member's current body parameters, click the “Member” button in the toolbar.

② In the member list (as shown below), double click the member to be examined to display the member name on the bottom right of this table, click the “Add” button below the physical examination record, fill in the weight in the popped-up parameter registration interface, and click “OK”.



Then fill the body parameters.



After completing the registration of the member's clinical information, preparations for the pre-examination shall be started.

(4) Examination

a. Examination precautions

① The examinee should not drink or do strenuous exercise 12 hours before examination.

② The examinee cannot have any symptom of the contraindication.

③ Since the HRA function test is a dynamic process, the examinee cannot move hands or feet and should keep good contact with the sensor during the examination.

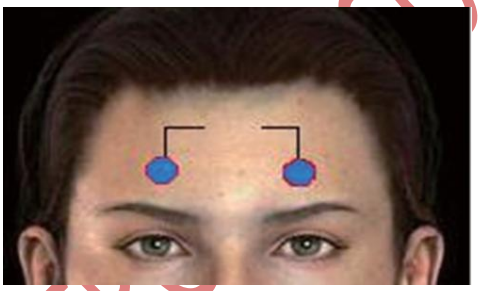
b. Pre-test preparation

① Before the test, disinfect hand and foot electrodes with 70% medical alcohol wipes at first, and then wipe using normal saline wipes.

② Ask the examinee to remove such metal accessories as mobile phone, watch and necklace to eliminate static electricity.

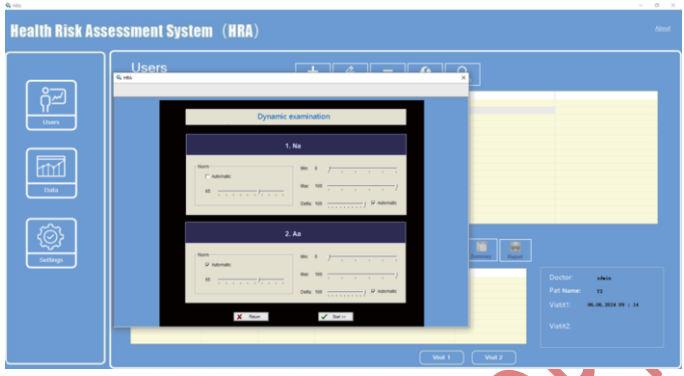
③ Deal with sweat and stains at the forehead, hands and feet which may influence the test result.

④ The examinee puts his/her hands and feet in the middle of the electrode, and pastes the disposable head electrode to the forehead, avoiding the hair and the eyebrow, as shown in the figure below:

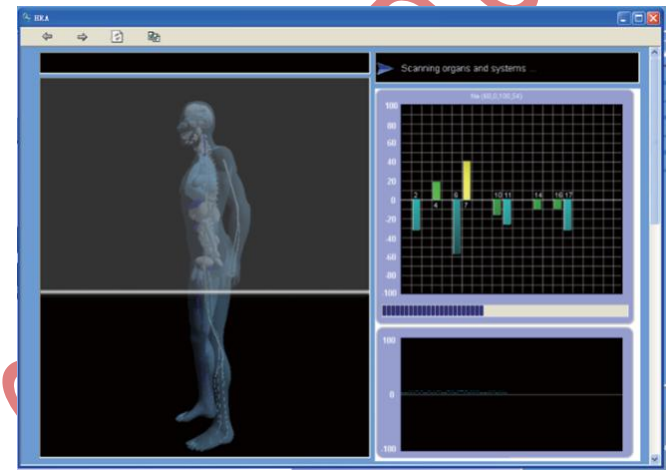


c. Dynamic examination

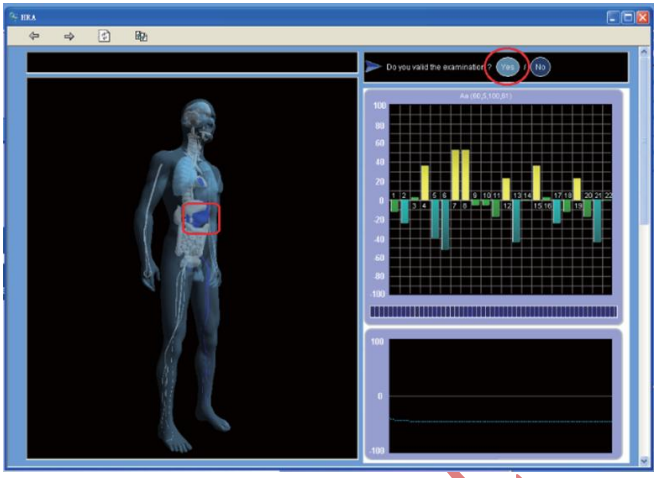
After completing the preparations before the examination, click the "Dynamic examination" button on the toolbar to enter the dynamic check interface as shown below:



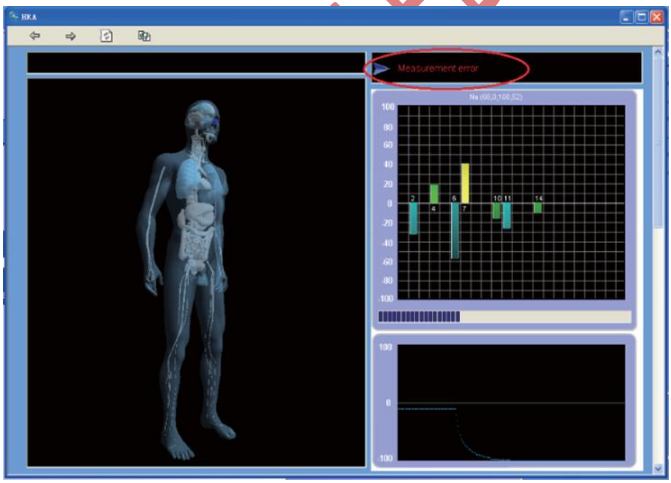
The information on the pop-up window is automatically generated for the system, no need to change, keep the default, click the “Start” button to enter the interface during the examination process, as shown below:



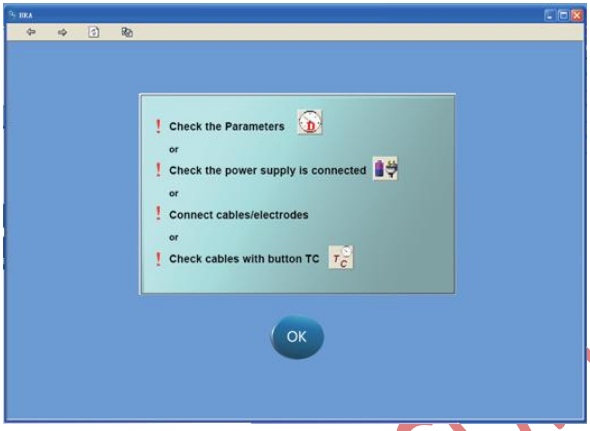
The examination includes 2 continuous processes: the standard mode and the automatic mode. During the examination, the area under scanning is displayed in blue. After the examination, click “YES” to save the examination data. As shown in the figure below:



If a cable connection error occurs during the examination, as shown in the following figure:



After about 5s, the system will pop up a dialog box to check as shown in the following figure:



According to the dialog box prompts to check, re-members of the dynamic examination, if the examination process is still the above errors, please contact manufacturers to resolve technical personnel.

(5) Print results

Confirmed the data was saved after examination, click the 

button to generate the examination result and to display the test report. The user can select to print and save the report.

(6) Close the program

If you want to exit the system, click the "Exit" ✕ button to exit the program.

I. Warnings and cautions

(1) The strong electromagnetic field will influence normal operation of the device. Please stay away from the strong electromagnetic field when it is installed and used.

(2) The device should be used by professionals trained by the manufacturer.

(3) It is forbidden to modify this device without authorization of the manufacturer.

(4) Remove the thin film before use, paste the disposable head electrode to the left and the right of the forehead. Before pasting please clean the forehead and wipe any sweat or stain to ensure firm contact. Do not reuse the disposable head electrodes to avoid any influence on the test result as well as cross contamination and infection, etc.

(5) The connecting lead shall be well connected to the disposable head electrode.

(6) To perform the test, please put hands and feet to the center of hand and foot electrodes, ensure complete contact. After the test is started, please keep still and do not move at random.

(7) The operator is suggested to observe data during the test after any test error. Please pay close attention if the value of several channels is below -85. If there are more than 3 such devices, the examinee may do not completely contact the device.

(8) Hand and foot electrodes shall be cleaned and disinfected after each test. Alcohol at the concentration of 70% can be used to wipe. Do not use any corrosive solution.

(9) Do not vigorously pull or fold the power line and other connecting lines to avoid damage.

(10) The user is suggested to change some parts of the device if the service time exceeds 10 years, to prevent potential safety hazards caused by aged components and parts.

(11) If any abnormal condition is observed during use, do not disassemble by yourself.

(12) Please cut off the power if the device will not be used for a long term.

J. Maintenance

(1) The device cannot be wiped by solvent or washed by water. The device can be wiped only by dry or wetted soft cloth. The device can be used only after it is dry. Equipment electrode plates disinfection should be disinfected with medical alcohol cotton ball, 70% medical alcohol, normal saline, disinfection steps in accordance with EN ISO 17664-2017 table A.1 requirements, as shown in the table below:

Table A.1--Cleaning and disinfection steps of the HRA system

Process	Process stage	Relevant aspect	Examples of information to be provided by the manufacturer, where applicable, including warnings and cautions	Recommended step YES/NO/N/A
Initial treatment at point of use	Remove contamination	Remove grosssoiling	— Wipe clean	Yes, clean it up
			— Rinse with water	
			— Flush channels	
			— Other	

Cleaning	Manual cleaning	Accessories	— Brushes (specify type, brush dimensions, filament types, etc. where relevant)	Yes, use soft dry/wet cloth for accessories
			— Spray gun or other flushing accessories, (including any minimum and/or maximum pressure)	
			— Any required dimensions for sinks, sink configuration, etc.	
			— Other special accessories	
		Water	— Water quality	
			— Any maximum temperature the medical device can withstand	
			— Volume requirements	
		Process chemicals	— Type of process chemicals to use (alkaline, acidic, neutral pH, enzymatic solution, enzymatic foam, or water only, etc.)	
			— Any parameters that might be different to those recommended or not specified by the process chemical manufacturer	
		Rinsing	— Any parameters that might be different to those recommended or not specified by the process chemical	

			manufacturer such as methods for determining adequate rinsing (minimum volume of water, time, etc.)	
Disinfection	Liquid chemical	Automated ormanual	— Compatible types of liquid chemicalsthat can be used (composition and active ingredient)	Yes, use medicalalcohol cotton ball, 70% medical alcohol, physiological saline to manually
			— Validated exposure time andtemperature to liquid chemical	

(2) The device shall be protected against dust, water, quake and high temperature. Note:

Only qualified personnel should repair the equipment or open the outer casing of the equipment to view the internal components of the equipment. Prohibited open any covers on the device. The operator cannot repair any components inside the device.

To assist the customer's professional technicians in repairing the repairable parts of the equipment, the company will provide the system's circuit diagram, component list, description, calibration instructions or other information upon request.

K. Common Trouble Shooting

If the software prompts that the device is disconnected during the test, the user can restart the computer and restart all devices of the system.

L. Storage

The packed product shall be stored in a well-ventilated room free from any corrosive gas at the temperature of -40℃-55℃, relative humidity of 10% - 95% and with the atmospheric pressure of 700 hPa - 1060 hPa.

M. Transportation

The packed product shall be transported as specified by the contract. The transportation environment should be -40℃-55℃, the relative humidity is 10%-95%,

and the atmospheric pressure is 700hPa-1060hPa. Rain- and snow-proof measures shall be adopted in the transportation process. Violent vibration and impact shall be avoided during loading and unloading.

N. Installation

Refer to the instruction manual for the installation steps.

Note: The product should be installed in a good environment. The size of the installation site should be no less than 2550mm long and 2120mm wide.

O. Environmental protection

Wastes, residues, etc., as well as equipment and accessories, should be disposed of in accordance with local laws and regulations and in compliance with correct environmental requirements after the end of their expected useful life.

HEALTH RISK APPRAISAL

HRA PORTABLE-01

MANUAL BOOK

Elitech®
TECHNOVISION